

REMARKS

Claims 1 and 3-18 are pending. Claim 1 has been amended by introducing the limitations of claim 2. Other amendments have been made to claim 1 to address the rejections under 35 U.S.C. §112, Second Paragraph. Finally, the term “suitable” has been removed from the claims. No new matter is introduced hereby.

Rejection under 35 U.S.C. §112, Second Paragraph

Claims 1 and 17 have been rejected as indefinite, because the term “the drug” in claim 1 allegedly lacks antecedent basis, and because the limitation “0.5 to 30% of the dry weight of the polymers by weight of the cores” appears to the Examiner to be unclear. The rejections are believed to be overcome for the following reasons.

The term “the drug” in claim 1 has been replaced by “a drug,” which finds support throughout the application as filed, both explicitly and implicitly. No new matter is believed to have been introduced by this amendment.

The term “0.5 to 30% of the dry weight of the polymers by weight of the cores” is believed to be clear in reference to claim 1, which recites “[a] coating composition, used for the film coating of pharmaceutical cores...comprising polymer...” and also considering the disclosure which points out at various points the weight of polymer used in various compositions as compared to the weight of the core. For example, in each Example, the amount of polymer applied as compared to the core weight was reported.

(Example 1, “[t]he total polymer content of the applied coat was 12.0% by weight of the core...[which] was sufficient to mask the bitter taste of Norfloxacin...;”

Example 2, “a 6% coating of polymers by weight of the core ... was sufficient to mask the taste of ibuprofen;” Example 3, “polymer coating of 12.0% by weight of the core was sufficient to mask the bitter taste of the drug;” Example 4, “the total polymer and solids applied were 8% and 17.5% by weight of the core, respectively which was sufficient to mask the taste of the drug without affecting the dissolution;” Example 5, “[t]he total polymer content of the applied coat was 11.90% by weight of the core.... The bitter taste of ciprofloxacin was masked with the applied coat without affecting dissolution;” Example 6, “[t]he total

polymer content of the coat applied was 12% by weight of the core. This coating effectively masked the pungent taste of paracetamol and also gave the desired dissolution profile...” Example 7, “total polymer application of 15% of the weight of the cores ... was sufficient to mask the bitter taste of ciprofloxacin without affecting the dissolution significantly.” emphases added).

The observations that dissolution profiles are not affected by the claimed coatings are in line with an aspect of the embodiments that are directed toward taste-masking as compared to, for example, controlled-release coatings.

Rejection Under 35 U.S.C. §102 (b) Over Jain et al. (United States Patent No. 4,610,870)

Claims 1, 4, 5, and 7-18 have been rejected as anticipated by Jain et al. Applicants respectfully traverse the rejection for the following reasons.

As pending claim 1 contains the limitations of claim 2 as filed, and claim 2 was not rejected as anticipated by Jain et al., there is no anticipation of the pending claim, and the Examiner is respectfully requested to reconsider and withdraw the rejection.

Rejection Under 35 U.S.C. §102 (b) Over Bai (United States Patent No. 5,840,329)

Claims 1-18 have been rejected as anticipated by Bai. Applicants respectfully traverse the rejection for the following reasons.

Bai discloses pre-programmed drug delivery systems including a plurality of particles, “divided into several delivery units, with each group having its own unique inner structured active core and specific external coating.” (col. 3, lines 49-51). The particles “contain an **outer coating** of a major portion of water-insoluble, water-permeable polymer, and a minor portion of water-insoluble, water-swellaable polymer, and water permeation adjusting agents...” (col. 3, lines 56-59; emphasis added). As Bai explains, in the preferred embodiment “major portion of water-insoluble, water-permeable polymer” means “from 80% to 99.9%” and “minor portion of water-insoluble, water-swellaable polymer” means “from 0.1% to 20%” (col. 8, lines 57-61).

The Examiner has pointed to particular disclosure in Bai which does not correspond to the composition of the “external coating layer” (col. 8, lines 46-51) as set forth by Bai. According to Bai, “[t]he external coating layer is comprised of a major

portion of water-insoluble, water permeable polymer; a minor portion of water-insoluble, water-swellaable polymer; and a water-permeation adjusting agent, either hydrophobic or hydrophilic in nature.” (col. 8, lines 46-51). Thus, the Examiner misapplies the disclosure of Bai to the instant claims.

The water-insoluble, water-permeable polymers (required to be present in a major portion by Bai) which are considered suitable by Bai are listed in col. 9, lines 23-46. There is no disclosure of “methacrylic acid copolymers, polymethacrylate-methylmethacrylate copolymers, alkyl celluloses or mixtures thereof,” as required by the pending claims.

The water-insoluble, water-swellaable polymers that swell upon contact with water (required to be present in a minor portion by Bai) which are considered utilizable by Bai are listed from col. 9, line 50 to col. 10, line 2.

Because there is no disclosure in Bai of required components of Applicants’ coating composition of pending claim 1, and because all other pending claims depend from claim 1, there is no anticipation of Applicants’ claims by Bai. The Examiner is respectfully requested to reconsider and withdraw the rejection.

CONCLUSION

The claims are believed to be patentably distinct from the cited references, and with this in mind, Applicants respectfully request a Notice of Allowance at the earliest opportunity.

Respectfully submitted,



George E. Heibel, PhD.
Reg. No. 42,648

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Correspondence Address:

Jayadeep R. Deshmukh, Esq.
Ranbaxy Inc.
600 College Road East, Suite 2100
Princeton, NJ 08540
Telephone: (609) 720-5608
Facsimile: (609) 514-9779